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David R. Hennings

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EXAMINER

SHAY, DAVID M

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/699,212	Applicant(s) HENNINGS ET AL.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 13, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-23 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-23 and 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of the response under 37 C.F.R. 111, as provided for in 37 C.F.R. 41.39(b)(1) filed on January 13, 2009, PROSECUTION IS HEREBY REOPENED. A response to applicant's submission is set forth below.

The examiner will first analyze the two declarations filed with the instant response:

The Hennings Declaration submitted January 13, 2009 (hereinafter The Hennings Declaration (2009)) begins by disclosing that Declarant is the C.E.O. of the assignee of the instant application and one of the instant inventors. Thus Declarant is not a disinterested third party. In paragraph 2, Declarant avers that he reviewed the Examiner's Answer mailed November 13, 2008. Declarant also asserts familiarity with the literature attached to the Geriack Declaration, submitted herein November 25, 2005. Declarant then, in paragraph 4 delineates his experience in the art. In paragraph 5, Declarant discusses his familiarity with the art of medical lasers and laser treatment of varicose veins. In paragraph 6, Declarant asserts that the scientific literature attached to the Geriak Declaration "are fully representative of the prior art with respect to varicose vein treatment". In paragraph 7, Declarant notes that the attachment to the instant Declaration, a true and accurate copy of an article by Dr.s Fan and Rox-Anderson (hereinafter Fan et al). The paragraph also describes Dr. Rox-Anderson as "one of the preeminent physicians in the field of interventional radiology, which includes the treatment of varicose veins". In paragraph 8, Declarant notes that Fan et al cite two of the articles to Proebstle et al attached to the Geriak Declaration and notes that other articles cited by Fan et al are from the same journal as the remaining article attached to the Geriak Declaration. In paragraph 9, Declarant notes that Fan et al also cite the patent to Navarro et al (U. S. Patent No. 6,398,777). Declarant also parenthetically asserts that the examiner states that Navarro et al is of "little moment" in the

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examiner's answer. The examiner respectfully notes that this assertion by Declarant is misleading. As the first paragraph on page 9 of the examiner's answer makes clear, the examiner was noting that appellant's arguments directed to a theoretical rejection constructed by appellant and which was never applied to the claims (and happened to involve Navarro et al) by the examiner during prosecution (and which rejection has still not been applied to the claims by the examiner) of the instant application were of little moment with regard to the issues actually before the Board. The paragraph is reproduced herein for applicant's convenience:

The examiner will note here that Appellants have devoted a portion of the Brief to discussion of the Navarro Patent, which has not been applied to the claims by the examiner. This "second guessing" of the rejection which, in appellants' opinion, the examiner should have applied to the claims is noted, however, is of little moment with regard to the analysis of the rejections which actually have been applied to the claims, and will not be discussed further herein.

Continuing in paragraph 9, Declarant notes that Fan et al "does not mention or cite any of the irrelevant prior art relied upon by the examiner". The examiner must first note that the judgment of the prior art cited by the examiner as "irrelevant" is an opinion on the part of Declarant, and is not supported by any evidence of record. The examiner must respectfully point out, that the issue of "relevance" with regard to an article drawn to the Mechanism of action of endovenous laser ablation is separate and distinct from the issue of "relevance" with regard to a rejection under 35 U.S.C. 103(a). Concluding paragraph 9, Declarant asserts that "the authors contrast the performance of a laser having a wavelength of 1320 nm with lasers having wavelengths of 810-1064 nm and conclude that there appears to be substantial patient benefit which results from the use of a wavelength of 1320 nm as recited in the claims of this application..." With regard to this statement, the examiner must respectfully note that the

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statement of Fan et al to which Declarant appears to be referring: “[A]t this higher wavelength and lower energy application, clinical evidence of perforation (pain, bruising) appears to be reduced.” (Fan et al, page 209, column 2, last sentence of the first full paragraph, parenthetical comment in original), does not mention that the benefit is “substantial”, further it is noted that the benefit (whether substantial or not) is attributed to “this higher [1320 nm] wavelength and lower energy”. It is respectfully noted that Affidavits must be drawn to the claimed invention: “An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness.” (see *In re Burckel*, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979)) and thus even to the extent that this statement can be interpreted as asserting non-obviousness (which Declarant has not clearly done) it can only be so interpreted for claims reciting not only 1320 nm (of which currently only claims 26-28 do), but also a specific lower energy (which none of the current claims do). As such the statement by Fan et al serves only to indicate that treatment at 1320 some undefined “lower fluence” and that perforation “appears to be reduced” (to what extent is unknown) and is insufficient to overcome the examiner’s prima facie case of obviousness. In paragraph 10, Declarant asserts that “I can state unequivocally that the Examiner was incorrect in refusing, at page 11 (sic, 9) of the Examiner’s Answer, to accept the assertions of our counsel, Mr. Geriak, that exhibits A, B, and C to his Declaration were representative of the prior art”. The examiner must take issue with this assertion. Firstly, the examiner must respectfully note that Declarant’s statement is simply opinion testimony, and as such “such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive.

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In re Chilowsky, 306 F.2d 908, 134 USPQ 515 (CCPA 1962)” (see MPEP 7.16.01(b)(III)).

Since the opinion is on the ultimate legal question at issue (whether or not the examiner should have accepted the arguments of Mr. Geriak, that the articles attached to the Geriak Declaration are representative of the prior art, when Mr. Geriak did not take the trouble to state such on the record as fact when writing the Declaration, but chose instead to state such solely in remarks attached to the submission to which the Geriak Declaration was also attached), it is entitled to no weight. It is also clearly set forth that arguments of counsel cannot take the place of evidence:

“The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.” (see MPEP 716.01(b)(II)). Examining the criteria set forth in *Chilowsky*, the examiner finds the opinion of Declarant to be unsupported by facts on the record and respectfully notes that no reason to waive the procedures set forth in MPEP 716.01(b)(II) has been asserted. Thus despite Declarant’s opinion, the examiner did not err in according the statements of Mr. Geriak with regard to the Declaration little weight. Lastly Declarant asserts his belief that the Fan et al article is “consistent with the fact that Exhibits A, B, and C attached to the aforementioned Geriak Declaration are representative of the prior art.” The examiner must respectfully note that as yet no “fact” that the Exhibits of the Geriak Declaration are “representative of the prior art” has been established with respect to the instant record, although the examiner does acknowledge that the

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Fan et al article is “consistent” with these articles being representative, at least as far as the articles being representative of art relating to the mechanism of action of endovenous laser ablation.

The Goldman Declaration begins by noting that Declarant is one of the coinventors of the instant application. In paragraph 2 Declarant acknowledges being one of the co-inventors of the base reference applied to the instant claims, U. S. Patent No. 6,258,084 to Goldman et al (hereinafter Goldman et al ('084)). In paragraph 3, Declarant asserts that VNUS Medical Technologies (which, though not indicated in the Declaration, is the assignee of record for Goldman et al ('084)), consulted with him regarding problems including lack of efficacy with the radio frequency technology for varicose vein treatment described by U. S. Patent No. 7,676,433 to Zikorus. However, the examiner must respectfully note that the highest number patent issued to date (March 10, 2009) is U. S. Patent No. 7,503,077. Thus the examiner will operate under the assumption that Declarant is referring to U. S. Patent No. 6,769,433 to Zikorus. In paragraph 4, Declarant that prior to working for VNUS, Declarant has successful experience in using tumescent anesthesia in ambulatory phlebectomy procedures, referring to three exhibits to demonstrate this. In paragraph 5, Declarant asserts that Goldman et al ('084) “involved only the use of tumescent anesthesia in the RF treatment of varicose veins and no work of any sort was done involving the use of lasers.” While this statement is noted, it is not clear that this “work” encompasses the entirety of the intellectual property circumscribed by the patent claims. For example, claim 31 and its dependents recite no limitation of application of tumescent anesthesia. Thus, while this may have been the area worked on by Declarant, it is not clear that the other three inventors in Goldman et al ('084) did not work on laser heating of the blood vessel.

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Continuing, Declarant states “Prior to filing the application which became U. S. Patent No. 6,285,084, we had no experience or knowledge which would permit us to enable the use of lasers to treat varicose veins.” While this statement is noted, there are several problems. Firstly, it is unclear what the antecedent of “we” is: would this Declarant and one other party? Two other parties? Were these parties also part of the inventive entity of Goldman et al (’084)? Were they the entirety of the inventive entity of Goldman et al (’084)? Secondly, this statement appears to be at odds with Declarant’s signature on the Declaration of Goldman et al (’084), which avers that Declarant has read and understood the specification thereof, including the claims, which specification included the reference to the use of lasers, and which claims were broad enough to encompass such use, by virtue of merely reciting an energy source, rather than the use of RF per se. Thus, weighing Declarant’s statement, wherein Declarant holds a vested interest in the issuance of the instant application, against the evidence afforded by a signed declaration in a U. S. Patent, with its attendant presumption of validity (which includes a presumption of operability), the examiner is not persuaded by Declarant’s current stance, that the subject matter of the claims of Goldman et al (’084) is inoperable. In paragraph 6, Declarant states that to the best of his knowledge, it was not until the laser treatment for varicose veins described in the Navarro et al patent (U. S. Patent No. 6,398,777, hereinafter Navarro et al) was developed that the first actual attempt to treat varicose veins endoluminally with lasers was made, while Declarant does not share that date when this technique “was developed” it is presumably prior to August 13, 1999, the filing date of Navarro et al. Declarant further notes that none of the technology was available to the “us” (again, the antecedent of this term is unknown, but presumed to include Declarant) when the work was done on Goldman et al (’084), and further

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notes that “Navarro took the wrong path” by using wavelengths in the range of 500-1100 nm. These opinions by Declarant are noted by the examiner, however, they are not born out by the disclosures of Navarro et al or Goldman et al ('084). As already discussed in the final rejection mailed February 12, 2007, Goldman et al ('084) clearly teach the desirability of heating the walls of the vessel and a careful inspection of Navarro et al reveals that this is also taught thereby, at column 3, lines 4-5: “a method that causes direct endothelial and vein wall damage”. As already iterated by the examiner, Sinofsky teaches the desirability of using wavelengths of approximately 1.4 to 2.2 micron (1400 to 2200 nm) to affect tissue via absorption by the chromophore water in the presence of blood, and Dew et al single out the use of the 1.32 micron wavelength to affect tissue that is covered with blood, noting the greater transmission through blood of this wavelength and its high absorption in water, as opposed to the 1.064 micron wavelength which is the dominant wavelength of the Nd:YAG laser. In paragraph 7, Declarant notes that the wavelength range of Navarro et al (which, the examiner notes, has still not been applied to the instant claims by the examiner) is not that of Declarant. And also notes that Navarro et al “considered it necessary for the fiber to contact the vessel wall”, however, the examiner has been unable to locate any discussion of the necessity of such a thing, although it is clearly disclosed by Navarro et al. And in paragraph 8, Declarant asserts that use of the wavelengths in the claimed range “was contrary to the view held by prior art workers that such wavelengths would be undesirable” asserting that such a view is expressed in the exhibits attached to the Geriak Declaration. However, Declarant has not established that the claimed wavelength ranges were “undesirable” in fact the examiner has found no derogatory or critical remarks, and Declarant has pointed to none, in any of Navarro et al, Goldman et al ('084), or any

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of the exhibits associated with the Geriak Declaration that relate to wavelengths in the claimed range. The mere fact that certain wavelengths were used does not, by itself, constitute an indictment of use of wavelengths not mentioned. For example, the use of 810 nm in exhibit A of the Geriak Declaration, is not a negative teaching with respect to the use of the 940 nm wavelength used in Exhibit C or vice versa. While they do teach the desirability of use of each of their preferred wavelengths neither cautions against the use of the other's. Thus the examiner cannot agree with the conclusion drawn in paragraph 8 by Declarant, as there is no solid factual basis therefor.

The examiner now turns to the arguments submitted with the Declarations. Firstly, applicant argues that Goldman et al ('084) does not enable the use of lasers. Leaving aside for the moment the fact that two of the named inventors of Goldman et al ('084), Mitchel P. Goldman and Robert A. Weiss, who presumably read and understood the specification and claims as filed, as specifically recited in the oath they signed in order to file the application that matured in the Goldman et al ('084) patent, are also named inventors in the instant application, there are still several deficiencies in this argument. One being that, at least as far as being a reference applied to the instant claims, Goldman et al ('084) does not need to enable the use of lasers for its own disclosure. Goldman et al ('084) need only enable one of ordinary skill in the art, in view of the knowledge already present in the prior art. As the instant application derives from a provisional application, filed October 31, 2002, publications prior to this date describe the state of the prior art with respect to the instant application. This would include publications such as the publication to Proebstle et al attached as Exhibit C to the Geriak Declaration, filed November 25, 2005, and attached as Exhibit 2 to the Brief on Appeal filed October 29, 2007.

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This publication, published in April of 2002, clearly discloses an endovenous method of treating varicose veins using a laser which “is a clinically feasible and well-tolerated technique” (See Proebstle et al, page 733, first paragraph under the DISCUSSION). Thus even assuming, *arguendo* that Goldman et al (‘084) is not enabled for the use of lasers (a contention that the examiner vigorously traverses), the disclosure of Goldman et al (‘084) is still sufficient, when read in light of the knowledge of one of ordinary skill in the art, to render the instant claims obvious under 35 U.S.C. 103(a), as evidenced by the disclosure of the use of lasers to provide the endovenous treatment by Proebstle et al prior to the earliest effective filing date of the instant application. Thus the assertion that Goldman et al (‘084) does not enable the use of lasers is not well founded. The specific arguments regarding the disclosure of Goldman et al (‘084) have been fully elucidated during the analysis of the Goldman Declaration. As the Declaration is not convincing, so too, are applicant’s arguments based thereon.

The examiner also re-iterates the arguments set forth in the examiner’s answer, as they are still germane. These arguments are herein repeated (with {bracketed} comments added for clarification) for applicant’s convenience:

Even though the primary embodiment of Goldman et al is related to RF, rather than laser, application to provide the desired treatment, the process Goldman et al wish to implement is clearly set forth: the method is aimed at either completely closing off (see column 2, lines 41-50) or greatly reducing, while still allowing to remain patent (see column 2, lines 51-65) the vein, or other anatomical tubular structure to be operated on; the vein is treated by applying energy to the vein wall, to shrink it (see Goldman et al column 5, lines 58-65), which energy, being applied to the vein wall, heats it and causes it to shrink (see Goldman et al column 9, lines 5-13 and column 13, lines 14-24); the device can then be pulled back to treat further portions of the vein (column 13, lines 15-30). The principles of the method having been disclosed to one of ordinary skill in the art, if it were desired to employ the laser embodiment of Goldman et al, one of ordinary skill in the art would, of necessity, look to the art of laser treatment to determine the appropriate parameters which would be required to fulfill the

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principles set forth in Goldman et al, e.g. providing energy to the vein wall to heat it and cause it to either shrink, or be completely occluded {this is considered to be the problem solved by Goldman et al ('084) and provides a motivation to one of ordinary skill in the art to locate lasers which perform thusly}. Sinofsky teaches a laser device to remove plaque from blood vessels or repair defects in small diameter artery walls (see column 1, lines 36-37) and for material removal and biological material repair (see column 2, lines 50-52), which repair can be effected by coagulation (see column 3, lines 25-28), which preferred laser wavelengths are in the range of approximately 1.4 to 2.2 microns and can be transmitted through blood (see column 4, line 47 to column 5, line 6). Sinofsky also teaches that one of ordinary skill in the art is familiar with the various calculations necessary to determine the appropriate parameters for providing a given amount of heat to the tissue being acted on (see column 10, line 50 to column 11, line 41), while these are couched in terms of the primary embodiment of vaporizing plaque, the equations could also be used to calculate the amount of heat necessary to provide tissue repair e.g. by coagulation of the tissue, as disclosed in a secondary embodiment of Sinofsky. Dew et al teaches that the extent to which tissue is heated by laser energy is dependant upon the extent to which the energy is absorbed by the tissue and notes that wavelengths that pass through blood relatively unattenuated, such as the 1.32 micron wavelength, are useful (see column 5, lines 47-65). Thus, clearly, the teachings of Goldman et al, taken with the knowledge of one of ordinary skill in the art, the use of the teachings of Dew et al and Sinofsky merely constitutes a predictable use of prior art elements according to their established functions (see KSR International Co. v Teleflex Inc. 82 USPQ2d 1385, 1396 (Supreme Court, 2007)).

Continuing, applicant argues that Sinofsky and Dew cannot properly be combined with

Goldman et al ('084). In order to bolster this line of argument, applicant doggedly focuses on the teaching of plaque ablation in Sinofsky, to the exclusion of all other teachings therein.

However, it is well recognized that "[A]ll of the teachings of a reference must be evaluated for what they fairly teach one of ordinary skill in the art" (see in re Boe, 148 USPQ 507) and further that "[A] a reference is not limited to its preferred embodiment, but must be evaluated for all of its teachings, including its teachings of non-preferred embodiments." (In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979)). Thus the teaching of providing tissue repair in Sinofsky, and the teaching of providing laser wavelengths which can be transmitted through blood to act on the desired tissue on the other side of the blood from the optical fiber, which have been

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repeatedly noted by the examiner, and steadfastly ignored completely by applicant, must be considered for what it would teach one of ordinary skill in the art with respect to repairing varicose veins “to cause them to durably assume the compressed diameter, such that when the effects of the tumescent anesthesia fluid are dissipated, the vein retains the compressed diameter” (see Goldman et al (‘084), column 5, lines 62-65) by shrinking, as taught by Goldman et al (‘084). Applicant then asserts that the examiner’s reliance on KSR International Co. v Teleflex Inc. 82 USPQ2d 1385 (Supreme Court, 2007), is “badly misplaced”, asserting that the Board relies on KSR for the proposition that there must be reasoning supported by rational underpinning to support an obviousness rejection and further citing *In re Kahn* (citation omitted) as exemplifying this. The examiner must respectfully point out that a rational underpinning has been supplied by the examiner: Goldman et al (‘084) seek to affect the vessel wall; Sinofsky teaches that wavelengths on the range of approximately 1400 to 200 nm can pass through blood and be used to ablate plaque or repair tissue, such as blood vessel walls, and Dew et al specifically teach that 1320 nm radiation is absorbed very little by blood, but highly by water, and as such can enable surgery on tissues even when they are obscured by blood. The examiner has set forth a clear rationale explaining why one of ordinary skill in the art would combine these references in the manner set forth in the rejection. Thus applicant’s wholesale dismissal of this clearly laid out line of reasoning as “a bare and baseless conclusory statement” (see the instant response, page 5, the last sentence thereon) is inaccurate. Applicant then, as Declarant Goldman, asserts that the exhibits attached to the Geriak Declaration teach against the use of the wavelengths in Sinofsky and Dew et al. As already set forth above, this is an overly generous interpretation of the teachings of these publications. None of the cited publications discourage

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the use of wavelengths not disclosed therein. The examiner has only relied on the teachings found in the prior art to construct the obviousness rejections applied to the claims

Next applicant asserts that the exhibits attached to the Geriak Declaration are representative of the prior art, since, this is set forth in the instant Declarations. This argument is not convincing for the reasons discussed regarding the Declarations themselves. Similarly, the fact that two of the exhibits attached to the Geriak Declaration are cited in foot notes in Fan et al does no more to further this proposition: Fan et al cite no less than 23 articles as foot notes, the fact that two of them mention certain wavelengths does not establish the use of these wavelengths to the exclusion of all others in the art. Nor does the fact that other cited references are from “the same journal” (see the Hennings Declaration (2009) paragraph 8) as the third, uncited publication which is attached to the Geriak Declaration serve to establish this assertion. In fact it is essentially contradicted by Fan et al, who state “[M]ost commonly, the commercially available lasers for EVLA are diode lasers (810, 940, and 980 nm) or Nd:Yag lasers (1064, 1320 nm)” (see Fan et al, page 207, column 1, last full paragraph, third sentence), thus while *some* of the lasers mentioned in the Geriak Declaration are among those “commonly used” in systems which are “commercially available” clearly the spectrum of lasers used are not limited to these, otherwise such a statement would not have been made in this regard by “one of the preeminent physicians in the field of interventional radiology” (see the Hennings Declaration (2009) paragraph 7).

Continuing, applicant asserts that the Fan et al article traces the evolution of “the energy based treatment of varicose veins from (a) RF heating to (b) the laser heating of Navarro (c) to the laser heating of the present invention” (see the instant response, page 6, fourth full paragraph,

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the penultimate sentence). The examiner must respectfully point out that applicant appears to have misconstrued the contents of the Fan et al article. The article begins “[E]ndovenous thermal ablation by either laser or radiofrequency ablation has emerged as an effective minimally invasive treatment of lower extremity superficial venous reflux disease...” (See the first page of Fan et al, column 1, first sentence), this is clearly not a dismissal of the use of RF, or of the lower wavelengths, it is simply a study to determine the mechanism of action of the treatment modality. Interestingly, the conclusion reached by Fan et al, is that the mechanism of action is the heating of the vein wall – the very same result desired by Goldman et al (‘084). Thus applicant’s argument that the examiner’s combination is “the creation of an imaginary universe which has no basis in fact and no rational underpinnings” must fail.

With regard to the Navarro et al, applicant asserts that the inclusion thereof in the footnotes of Fan et al as “strong confirmation” that “the move from RF treatment to laser treatment involved a choice of laser wavelengths...” However, as already set forth above, Fan et al describe no “move from RF treatment to laser treatment” but merely seek to determine the mechanism of action of the laser treatment. Therefore any conclusion predicated on this erroneous reading of Fan et al is similarly erroneous.

With regard to the asserted “uniform activity of others in the art” the examiner must again respectfully note that as Fan et al merely discuss these wavelengths as “commonly used” applicant is overreaching in characterizing the use of 810, 940, 980, and 1064 nm as “uniform activity of others in the art” while it may have been uniform to a majority of commercial vendors, it does not establish an absence of the use of any other wavelengths, either commercially or in research.

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Claims 1, 2, 6, 7, 25-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al. Goldman et al ('084) teach a method as claimed, including the use of tumescent anesthesia (see Abstract, second through fourth sentences and column 4, lines 43-60); heating the vessel wall to cause it to assume compressed dimensions, i.e. shrink (see Abstract, fifth and sixth sentences); moving the device in the vein to treat a larger segment thereof (Abstract, seventh sentence); and providing temperature sensors at the site (Abstract, last sentence); in the method of Goldman, the vein may be either partially or completely collapsed (see column 2, lines 41-65); this is achieved by applying sufficient thermal energy to shrink the tissue (see column 3, lines 52-56); and also involves removing a significant amount of blood from the area (column 3, lines 61-67); and that a laser may be used to provide the heating energy (see column 7, lines 53-59), but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art (see column 4, lines 47-65). Dew et al teach the desirability of using 1.32 micron radiation to treat tissue (see column 5, lines 41-65). It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take its place (see Dew et al column 11, lines 37-44), and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, thus producing a method such as claimed.

Claims 3-5, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew as applied to claims 1, 2, 6, 7, 25-38, 40, 41, and 44-46 above, and further in view of Roth et al. Roth et al teach employing pull

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back rate as claimed, noting that the desired rate is dependent on the laser energy (see column 15, lines 24-50). It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art of which is hereby taken, thus producing a method such as claimed.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed. It would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue (see page 2, first full paragraph), thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing (see the paragraph spanning pages 15 and 16). It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed (see page 13, second full paragraph for the fiber and introducer; page 20, first full

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paragraph for the means for administering anesthesia; and the thermal sensor is disclosed at the paragraph spanning pages 15 and 16, as above) except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al, since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber (see figure 5 and the paragraph spanning pages 14 and 15). It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

The response to the arguments set forth in the Brief on Appeal which were rendered in the Examiner's Answer are herein repeated:

Preface

Appellants have three main points of argument:

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a) Only the preferred embodiment of using RF energy to treat the varicose vein is enabled, while the secondary embodiment of using laser energy to provide the ligation of the vein is not enabled;

b) The remaining references with which Goldman et al is combined do not teach the treatment of varicose veins; and

c) Appellants feel the examiner has refused to consider the evidence submitted by appellants to establish non-obviousness of the claimed invention.

The examiner will note here that Appellants have devoted a portion of the Brief to discussion of the Navarro Patent, which has not been applied to the claims by the examiner. This “second guessing” of the rejection which, in appellants’ opinion, the examiner should have applied to the claims is noted, however, is of little moment with regard to the analysis of the rejections which actually have been applied to the claims, and will not be discussed further herein.

a) Goldman et al is enabled for laser application

b) The teachings of the secondary references

As the teachings of the secondary references are properly combined with Goldman et al, both because they are from the laser surgery field, which Goldman et al points to by discussing lasers, and because they deal with the removal or repair of tissue in tubular organs, which Goldman et al teach, without limitation to blood vessels per se, the fact that they do not explicitly teach the treatment of varicose veins is not a bar to their combination with Goldman et al.

c) The examiner has given due consideration to the evidence submitted by appellants

Appellants assert that the examiner has “refused to consider” the evidence proffered to establish non-obviousness. The examiner must respectfully disagree. The examiner must first point out that the contents and teachings of the articles were analyzed in the rejection mailed May 17, 2006 in the paragraph bridging pages 2 and 3 thereof. However, appellants have neglected to discuss this treatment of the submissions, instead preferring to focus on the examiner’s comment in the subsequent rejection, the final rejection mailed February 12, 2007.

It is important to note that the articles and product information were submitted with Affidavits and that all Affidavits only aver that the submissions are “true copies” of the articles or product literature which is described in the Affidavits. There is no assertion whatsoever in any Affidavit of record that the articles or product literature are in any way representative of the prior art with respect to varicose vein treatment. Instead such assertions are made only in the remarks accompanying the affidavits. This is interesting, given that these remarks bear the signature of Mr. Geriak, one of the affiants. However, as these assertions are only submitted in the form of remarks accompanying a response, they cannot be elevated to the status of evidence. As such, these remarks are noted, but do not speak to the propriety of the combination which the examiner has applied to the claims.

Next appellants admonish the examiner for the “summary refusal” to consider the evidence submitted, citing In re Sullivan. The examiner respectfully submits that the evidence, that is to say the articles and product literature per se, as well as the accompanying remarks were considered and evaluated in the rejections mailed May 17, 2006 and February 12, 2007. Thus appellants’ characterization of the examiner’s actions as a “summary refusal” to consider the

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evidentiary submissions is simply inaccurate, and the citation of *Sullivan* (presumably *In re Sullivan* 84 USPQ2d 1034), which deals with the dismissal by the Board of Affidavit evidence that was not commensurate in scope with the claimed invention; wherein the case was returned to the examiner, and further prosecuted, with the claims being then amended to recite the invention as a pharmaceutical compound for a particular type of treatment discussed in the Affidavit evidence, then returned to the Board, which deemed the particular treatment an intended use and again did not consider the Affidavit evidence; is not on point, as it does not conform to the fact pattern herein.

D) Rejection Of Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky and Dew et al

As set forth above under a), the prior art is properly combinable and properly combined so as to establish a *prima facie* case of obviousness. Appellants characterize the disclosure of the use of a laser to heat the blood vessel wall as “no more than a throw away mention of lasers”. However, this is clearly not the case. The use of a laser is clearly set forth as an equivalent alternative to the RF method more thoroughly described, as well as the resistive, microwave, ultrasound, and other types of tissue heating devices set forth in Column 7 of Goldman et al. It is a well understood point of law that “All of the disclosures in a reference must be evaluated for what they would fairly teach one of ordinary skill in the art. Thus in [citations omitted] this court affirmed rejections based on art which we concluded rendered the claimed invention obvious to those of ordinary skill in the art despite the fact that the art teachings relied upon in all three cases were phrased in terms of a non-preferred embodiment...” (see *In re Boe* 148 USPQ 507).

Thus appellants' extensive discussion of the teachings of references not applied to the claims, which noted that the primary mechanism for destroying the vessel was due to the heating of the blood by the various wavelengths employed by the references not applied to the claims, is insufficient to rebut the *prima facie* case of obviousness, based on, among other things, the express teaching in Goldman et al that the tissue desired to be heated is the vein wall. Thus these arguments are not convincing.

II) Claims 3-5, 42, And 43 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky Dew et al and Roth et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

III) Claims 8 and 39 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Conn et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

IV) Claims 9-13 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Makower et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

B) Claims 14 And 18 Are Obvious Over L'Esperance in Combination With Kohayakawa and Bille et al ('340)

The arguments with regard to claim 14 are predicated on the use of a sensor, as argued with respect to claim 1, and are not convincing for the same reasons.

V) Claims 14-17 And 20-23 Are Obvious Over Makower et al in Combination With Roth et al, and Dew et al

With regard to the combination involving Makower et al Roth et al and Dew et al, appellants argue that none of the reference deal with the intended use of the device. The examiner respectfully notes that to render an apparatus claim obvious, it is merely necessary that the examiner provide a *prima facie* case of obviousness for the structure claimed, not the method envisioned by appellants. As set forth above, Makower et al teach a device including an introducer, an optical fiber and a means that can be used to administer anesthetic. Since Makower et al provide no wavelength information, one of ordinary skill in the art would be motivated to employ the versatile laser of Dew et al, which could not only provide the main wavelength suggested by Roth et al, but also the 1.32 micron wavelength that could be used to seal the holes discussed in the first full paragraph of page 16 of Makower et al, which would further reduce the chance of infection therefrom.

Appellants also postulate that a pull back mechanism is incompatible with the Makower device, which includes a locking mechanism. However, a careful reading of the Makower et al reference reveals that the locking mechanism only locks the cannula, as can be seen by the disclosure that the fiber can be completely removed and reinserted while the cannula is locked in place (see Makower et al, page 20, first full paragraph), thus no incompatibility exists, and the pull back device would allow for the treatment of a length of the prostate without removing and re-situating the cannula. Thus this argument is not convincing

B) Claim 19 Is Obvious Over Makower et al in Combination With Roth et al, Dew et al, and Conn et al

With regard to this combination, appellants have argued that none of the references of the base combination call for a diffuser. However, since one of the many embodiments of Makower et al involves photodynamic therapy (see Makower et al, page 20, second sentence) and the diffuser of Conn et al may be employed for photodynamic therapy, (see page 1, the first sentence under “BACKGROUND AND SUMMARY OF THE INVENTION”) this argument is not convincing.

Appellants have requested an affidavit from the examiner with respect to the problem of tissue adhesion. However, given that the official notice was taken in the very first office action, in July of 2004, and since appellants have received four office actions in the interim, the request is not seasonable. Even assuming, arguendo, that the request was seasonable, this appears to be a moot point, since Goldman et al specifically teach the use of a pull back mechanism.

With regard to the statistical significance of the number of articles drawn to the treatment of varicose veins, the examiner submits that the dozens of articles referenced in the bibliographies of the submitted articles provide an indication of the amount of literature that exists concerning this subject. The examiner would venture that each of these dozens of articles would cite other articles in the field. If appellant has knowledge to the contrary, appellants may submit an affidavit to the effect that this literature is the sum total of all literature in the field of varicose vein treatment.

Applicant's arguments filed January 13, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769